



6111 Broken Sound Parkway NW
Boca Raton, FL 33487-3693
(561) 241-9400
Fax (561) 995-5188

1019 1019-1019

August 18, 1999

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug and Cosmetic Act that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Acidophilus XTRA: For healthy digestive function. Intestinal flora plays a major role in your nutritional status and affects immune system function, cholesterol, metabolism, cellular health, as well as aging. This pro-biotic supplement can be effectively used to provide overall good health.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

A handwritten signature in cursive script, appearing to read "Deborah Shur Trinker".

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure